UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,795	07/02/2003	Guy Vanney	2097/US	7349

33486 7590 02/21/2006

HEIMBECHER & ASSOCIATES, LLC.
390 UNION BLVD
SUITE 650
LAKEWOOD, CO 80228-6512

EXAMINER	
PEFFLEY, MICHAEL F	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,795	VANNEY, GUY	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/29/04 1/30/04 2/2/04 2/3/04 (s)
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 lacks proper antecedent basis for "the output port" (line 8) which should apparently read "the outlet port".

Claim 7 lacks proper antecedent basis for "the electrode lumen" and should apparently depend from claim 6 (and not claim 5) where proper antecedent basis is provided.

Similarly, claim 9 should depend from claim 8 (and not claim 7) to provide proper antecedent basis for "the channel". It would also be clearer if "the channel" were amended to recite "the at least one channel" to be more consistent with the language of claim 8.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Brucker et al (5,462,521).

Brucker et al disclose a catheter ablation apparatus that includes a tubular body (22) having a manifold (distal tip 50 of Figure 9). Ablation fluid (i.e. saline) flows through the manifold, and the manifold comprises an inlet port (60 – Figure 9) in communication with a fluid supply (54) and an outlet port (58) in communication with the inlet port and having a larger dimension than the inlet port. The entire tip member (50) is an electrode and is therefore in the ablation fluid path. The examiner maintains that the enlarged opening (58) relative to the inlet path would inherently provide a swirling of the fluid, and either of the "x" or "y" axis in Figure 9 could be deemed the "longitudinal axis" to thereby meet the limitations of claims 2 and 3. The electrode (50) is housed in an electrode lumen (28) of the catheter (22), and the electrode lumen (28) is in fluid communication with the outlet ports. The manifold further includes a channel (54) that is in fluid communication with the outlet port, the channel also being located within the channel (28) in the catheter.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Swartz et al (6,080,151).

As shown in Figure 10, Swartz et al provide an ablation catheter including a tubular body (300) having a manifold (304) in the body. The manifold includes a plurality of inlet ports (306) that communicate with exit ports (310), whereby the exit ports are larger than the inlet ports. Swartz et al disclose inlet and outlet ports in the size limitations set forth in claim 5 (see col. 7, lines 65-67 and col. 11, lines 7-16). Manifold (304) includes an electrode (302) housed in a lumen of the catheter, and there

is a channel extending into the manifold (304) for delivering fluid through the inlet ports (306).

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Tu et al (5,792,140).

As shown in Figure 1, Tu et al disclose an ablation catheter having a tubular body (1) and a distal arcuate section (2). Figure 3 shows a lumen within the tubular body and a manifold means (including the unlabeled delivery line and ports 20) for conveying fluid from within the catheter lumen to tissue.

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Bednarek et al (6,120,500).

Bednarek et al disclose a tubular body (14) having an arcuate distal section (18) as shown in Figure 2. Figure 11 shows the manifold system including means to deliver fluid from within internal lumen (40) through openings (38) to outside the tubular body.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brucker et al ('521) in view of the teaching of Swartz et al ('151).

The Brucker et al device has been addressed above. Brucker et al fail to disclose the specific size limitations for the inlet and outlet ports. The examiner maintains that one of ordinary skill in the art would recognize the various sizes that may advantageously be used in such a system.

As evidence to that fact, Swartz et al disclose an analogous fluid delivery ablation catheter and specifically indicate size limitations for the inlet and outlet openings that are within the range set forth in applicant's claim 5. The size of the openings serves to control the flow of fluid from the device.

To have provided the Brucker et al device with any reasonably sized lumens to control the delivery of fluid to tissue during the ablation procedure would have been an obvious modification for one of ordinary skill in the art, particularly in view of the teaching of Swartz et al.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al ('151) in view of the teaching of Bednarek et al ('500).

Swartz et al, as addressed previously, fail to specifically show a curved catheter tip. In as much as the Swartz et al catheter is used in cardiac procedures, it is presumably flexible and able to be placed in arcuate positions to treat tissue. However, to further illustrate that it is known to provide such a catheter with an arcuate shape to treat cardiac tissue, attention is directed to Bednarek et al.

The Bednarek et al device is substantially identical to the Swartz et al device and is used in treating cardiac tissue (just as the Swartz et al catheter is used). In particular, Bednarek et al teach that it is known to provide the catheter with an arcuate distal shape (Figure 2) to facilitate placement at certain cardiac locations.

To have provided the Swartz et al device with an arcuate distal section to facilitate the catheter's placement at desired cardiac locations would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Bednarek et al.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Numerous patents and publications have been issued to inventor Vanney including US Patent Numbers 6,960,207 and 6,984,232 and US Publication Numbers 2004/0143253; 2005/0267463 and 2005/0004516.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Peffley
Primary Examiner
Art Unit 3739

mp
February 15, 2006